



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/333,256	06/15/99	ENGEL	J PM26021897/2

HM22/1107
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EXAMINER

TRAN, S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Supplemental
Office Action Summary

Application No.
09/333,256

Applicant(s)

Engel et al.

Examiner

Susan Tran

Group Art Unit

1615



☒ Responsive to communication(s) filed on Aug 28, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99, Requested for Extension of Time and Amendment A filed 08/28/00.

Information Disclosure Statement

1. The information disclosure statement filed 10/24/00 fails to recite the date of publication of each reference. It has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments

2. Applicant's arguments filed 08/28/00 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al. 5,905,149 ('149), in view of Eugster et al. USPN 5,593,691 ('691).

Applicants argued that Battistini mentioned cyclophosphamide only as part of a hypothetical combination. However, the examiner refers to the teaching in column 11, lines 64 through column 12, lines 4-10, wherein Battistini teaches the additional pharmaceutical agents such as cyclophosphamide can be used with compound of formula (I) as a combined formulation. Hence, it is the examiner's position that such language does indicate the present of cyclophosphamide in the tablet.

Art Unit: 1615

Applicants argued that Eugster does not disclose solid compositions at all. However, the examiner refers to the teaching in column 20, lines 48-52, wherein Eugster teaches a solid dosage forms for oral administration such as tablet, granules, pellets, powders, or capsules.

Applicants argued that the cited references disclosed preswollen corn starch. However, the burden is shifted to applicants to provide a side by side comparison of the results from a non-preswollen starch against the generic teaching of the prior art. Further, Eugster teaches in column 8, lines 40-48, wherein the composition has excellent stability and bioavailability of the active substances; column 22, lines 5-10, the use of stabilizers to improve stability of the composition.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1615

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600